DATA EVALUATION RECORD
72-1(C)/850.1075 -- ACUTE LC_{50} TEST WITH A COLDWATER FISH

1. **CHEMICAL:** 1,2-Benzenedicarboxaldehyde (ortho-phthalaldehyde) PC Code.: 129017

2. **TEST MATERIAL:** Ucarcide P200 MUP Purity: 99.8 %

3. **CITATION**

Authors:	Holtze, K.
Title:	Ortho-Phthalaldehyde: Ecotoxiological Evaluation of Acute Toxicity to Rainbow Trout (*Oncorhynchus mykiss*)
Study Completion Date:	May 16, 2002
Laboratory:	ESG International, Inc., Guelph, Ontoario, Canada
Sponsor:	The Dow Chemical Company, Piscataway, NJ
Laboratory Report ID:	S2041-02
MRID No.:	457026-01
DP Barcode:	325167

4. **REVIEWED BY:** Srinivas Gowda, M.S., Biologist, RASSB, AD

Signature: **Date:**

5. **APPROVED BY:** Norm Cook, Branch Chief, RASSB, AD

Signature: **Date:**

6. **STUDY PARAMETERS**

Scientific Name of Test Organism:	*Oncorhynchus mykiss*
Age or Size of Test Organism:	juvenile (5 ± 1 cm)
Definitive Test Duration:	96 hours
Study Method:	Static Renewal
Type of Concentrations:	Mean measured - Time-weighted

7. **CONCLUSIONS:**

Results Synopsis

LC_{50}: 0.02 mg ai/L 95% C.I.: 0.013 - 0.026 mg ai/L

NOAEC: 0.013 mg ai/Li Probit Slope: n/a

8. **ADEQUACY OF THE STUDY**

A. Classification: Supplemental

B. Rationale: The loss of chemical over time and the subsequent use of time-weighted average concentrations for determining the endpoints may cause an underestimation of the actual toxicity level of this chemical..

C. Repairability: Not repairable

9. GUIDELINE DEVIATIONS

1. Concentrations of the test chemical decreased over time during the test. Since the limit of quantification (LOQ) was 0.1 mg/L, concentrations of concentrations below this level were estimated using the measured values which exceeded the LOQ. All concentrations were then time-weighted for use in endpoint calculations.

2. Temperature was measured daily, not continuously in one test vessel as recommended in the Guidelines.

10. SUBMISSION PURPOSE: Submitted as FIFRA 6(a)(2) information for a manufacturing use product (MUP) used to formulate materials preservatives.

11. MATERIALS AND METHODS

A. Test Organisms

Guideline Criteria	Reported Information
Species Preferred species is the rainbow trout (*Oncorhynchus mykiss*)	rainbow trout (*Oncorhynchus mykiss*)
Mean Weight 0.5-5 g	0.79 ± 0.51 g (ranged 0.44 - 1.34)
Mean Standard Length Longest not > 2x shortest	Mean Fork Length : 44.2 ± 8.8 mm Range:37 - 52 mm Mean total length 5 ± 1 cm
Supplier	Rainbow Springs fish hatchery
All fish from same source?	Yes
All fish from the same year class?	Yes

B. Source/Acclimation

Guideline Criteria	Reported Information
Acclimation Period Minimum 14 days	14 days
Wild caught organisms were quarantined for 7 days?	N/A
Were there signs of disease or injury?	No
If treated for disease, was there no sign of the disease remaining during the 48 hours prior to testing?	N/A
Feeding No feeding during the study	Last feeding 24h pre-test; not fed during test
Pretest Mortality < 3% mortality 48 hours prior to testing	0.52 % mortality in 7 days prior to testing.

C. Test System

Guideline Criteria	Reported Information
Source of dilution water Soft reconstituted water or water from a natural source, **not** dechlorinated tap water	Well water; initial hardness 242 mg/l as $CaCO_3$, initial pH 8.3
Does water support test animals without observable signs of stress?	Yes
Water Temperature 12EC	15 $\pm$ 1EC
pH Prefer 7.2 to 7.6	
Dissolved Oxygen Static: $\exists$ 60% during 1st 48 hrs and $\exists$ 40% during 2nd 48 hrs, flow-through: $\exists$ 60%	lowest DO was 9.1 mg/L at 96 hours in both control replicates

Guideline Criteria	Reported Information
Total Hardness Prefer 40 to 48 mg/L as $CaCO_3$	mg/L as $CaCO_3$
Test Aquaria 1. Material: Glass or stainless steel 2. Size: Volume of 18.9 L (5 gal) or 30 x 60 x 30 cm 3. Fill volume: 15-30 L of solution	5 gallon glass aquaria containing 15 L of solution 15 L
Type of Dilution System Must provide reproducible supply of toxicant	static renewal
Flow Rate Consistent flow rate of 5-10 vol/24 hours, meter systems calibrated before study and checked twice daily during test period	N/A
Biomass Loading Rate Static: # 0.8 g/L at # 17EC, # 0.5 g/L at > 17EC; flow-through: # 1 g/L/day	0.53 g/L
Photoperiod 16 hours light, 8 hours dark	16 h light, 8 h dark w/ 30-min dusk/dawn transition
Solvents Not to exceed 0.5 ml/L for static tests or 0.1 ml/L for flow-through tests	Solvent: none

D. Test Design

Guideline Criteria	Reported Information
Range Finding Test If LC_{50} >100 mg/L with 30 fish, then no definitive test is required.	96-hLC50 was between 0.1 and 1.0 mg ai/L (nominal) (mortality was 10% and 100%, respectively)
Nominal Concentrations of Definitive Test Control & 5 treatment levels; dosage should be 60% of the next highest concentration; concentrations should be in a geometric series	control, 0.0625, 0.125, 0.25, 0.5 and 1.0 mg ai/L
Number of Test Organisms Minimum 10/level, may be divided among containers	10/replicate, 2 replicates/level
Test organisms randomly or impartially assigned to test vessels?	Yes
Biological observations made every 24 hours?	Yes
Water Parameter Measurements 1. Temperature Measured constantly or, if water baths are used, every 6 hrs, may not vary > 1EC 2. DO and pH Measured at beginning of test and ever 48 h in the high, medium, and low doses and in the control	pH, DO, conductivity, temperature and visual observations at 0, 4, 24, 48, 72, and 96 hours
Chemical Analysis Needed if solutions were aerated, if chemical was volatile, insoluble, or known to absorb, if precipitate formed, if containers were not steel or glass, or if flow-through system was used	200 mL collected from control and all test concentrations at beginning and end of each 48-hour period (initial and renewed solutions). Samples were analyzed for ortho-pthalaldehyde (OPA) concentration using HPLC.

12. REPORTED RESULTS

A. General Results

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes
Recovery of Chemical	Concentrations of OPA declined during each 48-hour period. The measured values in the three highest concentrations were used to extrapolate the lower concentrations, since the lower concentrations had declined to below the limit of detection. By 48-h, the detected concentrations of OPA in the nominal levels of 0.25, 0.5, and 1.0 mg/L were 0.03, 0.04 and 0.13 mg/L, respectively (12, 8, and 13 % of nominal, respectively).
Control Mortality Not more than 10% control organisms may die or show abnormal behavior.	0 %
Raw data included?	Yes
Signs of toxicity (if any) were described?	Yes

Mortality

Concentration (mg/L)		Number of Fish	Cumulative Number Dead			
			Hour of Study			
Nominal	Time-weighted average concentration		24	48	72	96
Control	--	20	0	0	0	0
0.0625	0.013	20	0	0	0	0
0.125	0.026	20	1	6	12	17
0.25	0.055*	20	20	20	20	20
0.5	0.04*	20	20	20	20	20
1.0	0.13*	20	20	20	20	20

* concentrations with 100% mortality by 48-h were not continued to 96-h. Chemical

concentration results were predicted to follow the same pattern seen in the initial 48-h--the values from the 3 highest concentrations were used to extrapolate the concentrations in the lower concentrations.

Other Significant Results: Clinical signs of toxicity were observed in fish at the 0.125 mg/L level. One fish showed darkening at 48-h, 1 fish showed darkening and 3 showed darkening plus immobility at 72-h, and 3 showed darkening at 96-h.

B. Statistical Results

Method: Stephan program--binomial method

96-hr LC_{50}: 0.02 mg OPA/L 95% C.I.: 0.013 - 0.026

Probit Slope: n/a NOAEC: 0.013 mg OPA/L

13. VERIFICATION OF STATISTICAL RESULTS

Parameter	Result
Binomial Test LC_{50} (C.I.)	0.02 mg OPA/L (0.013 - 0.026)
Moving Average Angle LC_{50} (95% C.I.)	not reliable for this data set
Probit LC_{50} (95% C.I.)	not reliable for this data set
Probit Slope	n/a
NOAEC	0.013, based on signs of toxicity

14. REVIEWER'S COMMENTS: This study is scientifically sound, but does not fulfill the Guideline requirements for a freshwater fish acute toxicity study. The loss of chemical over time and the subsequent use of time-weighted average concentrations for determining the endpoints may cause an underestimation of the actual toxicity level of this chemical.

Sign-off Date : 01/18/06
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